PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE of persons are required to respond to a collection of information unless it contains a valid OMB control number.

Under the Paperwork Reduction Act of 1995, no perso

Substitute for form 1449A/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet of 8

		_
	Complete if Known	_ `
Application Number	10/042,226	
Filing Date	January 11, 2002	
First Named Inventor	Bernd RIEDL et al.	
Group Art Unit	1614	
Examiner Name		
Attorney Docket Number	BAYER-0024-A	

	U.S. PATENT DOCUMENTS					
	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication of	Pages, Columns, Lines, Where Relevant	
Examiner Initials *	Cite No. <sup>3</sup>	Number Kind	Code <sup>2</sup> own)	of Cited Document	Cited Document MM-DD-YYYY	Passages or Relevant Figures Appear
		4,546,191				
	-	5,559,137	-			
	<b>!</b>	6,280,218	<b></b>			
		3,284,433	+			
		5,510,004				
		6,310,068				
		6,525,046				
		6,500,863				

			FC	DREIG	N PATENT DOCUME	NTS		_
Examiner Initials*	Cite No.'	Foreig Office <sup>3</sup>	er <sup>4</sup> (if k	Code <sup>5</sup>	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sub>6</sub>
		EP	0690344					
		WO	02/002576			<u> </u>		
Hat		wo	02/062763	A2	Bayer Corp.	8-15-2002		
50 A		wo	02/083628	Al	Boehringer Ingelheim Pharmaceuticals Inc.	10-24-2002		
20A		wo	02/085857	A2	Bayer Corp.	10-31-2002		
208		wo	02/085859	A1	Bayer Corp.	10-31-2002		
200		wo	97/09973		The Regents Of The University Of California	3-20-1997		
-		Wo	08/20868	ļ				
		WO	08/45268					
		<del>  wo</del>	99/28305					
			00/14244					
1-11		WO	02/14/311					
		+ wo	00/56331			ļ		
		WO	03/000771					
		EP	0709225	D1				

Examiner Signature	/James Anderson/	Date Considered	04/19/2007

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

<sup>&</sup>lt;sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 3 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark hee if English language Translation is attached.

Substitute for form 1449A/PTO Complete if Known 10/042,226 **Application Number** INFORMATION DISCLOSURE January 11, 2002 Filing Date STATEMENT BY APPLICANT First Named Inventor Bernd RIEDL et al. Group Art Unit 1614 (use as many sheets as necessary) Dwayne C. Jones **Examiner Name** of 8 Attorney Docket Number BAYER-0024-A Sheet

Examiner Cite No.1		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
/JDA/		Blanco, "p38 MAPK signaling cascades: ancient roles and new functions," Bioassays, 22:637-645, 2000	
		Dumas, J. "Protein Kinase Inhibitors from the urea class," Curr. Opin. In Drug Discovery and Dev., 5:718-727, 2002	
		Hotte et al., "Bay 43-9006: Early clinical data in patients with advanced solid malignancies," Current Pharmaceutical Design, 8:2249-2253, 2002	
		Kubo et al. "Synthesis and structure-activity relationship of quinazoline-urea derivatives as novel orally active VEGF receptor tyrosine kinase selective inhibitors," Proceedings of the American Association of Cancer Res. 43:182, 2002	
		Madwed et al., "Pharmacological Evaluation of BIRB 796, a selective inhibitor of P38 MAP kinase (MAPK), in animal models of endotoxic shock, inflammation and arthritis," Inflammation Res., 50:S184, 2001	
		Regan et al., "Pyrazole urea-based inhibitors of P38 MAP kinase: from lead compound to clinical candidate," J. Med. Chem. 45:2994-3008, 2002	
		Proceedings of the American Association for Cancer Research - Volume 42 - March 2001 - #4954 Anti-Tumor Efficacy of the Orally Actibe Raf Kinase Inhibitor BAY 43-9006 in Human Tumor Xenograft Models. Christopher A. Carter et al., Bayer Corporation.	_
	•	XP-001145779 "Antitumor Activity of a C-raf Antisense Oligonucleotide in Combination with Standard Chemotherapeutic Agents against Various Human Tumors Transplanted Subcutaneously into Nude Mice", Thomas Geiger et al., Vol. 3, 1179-1185, July 1997.	
		XP-002232130, "A Phase I Trial of H-ras Antisense Oligonucleotide ISIS 2503 Administered as a Continuous Intravenous Infusion in Patients with Advanced Carcinoma", C. Casey Cunningham et al., 2001 American Cancer Society, Volume 92, Number 5, pages 1265-1271.	
		Riedl et al., Potent Raf Kinase Inhibitors from the Diphenylurea Class: Structure Activity Relationships," Proc. Amer. Assoc. Can. Res., 42:923, 2001	
		XP-001145481 +2921 Phase I and Pharmacokinetic Study of the Raf Kinase Inhibitor Bay 43- 9006 in Patients with Locally Advanced or Metastic Cancer," Proceedings of the Annual Meeting of the American Association of Cancer Research, 42:543, 2001, Dirk Strumberg et al., Bayer AG.	
$\bigvee$		Garcia-Lopes et al., "New routes for the synthesis of pyrrolo(3,2-d)- and (2,3-d)- pyrimidine systems starting from a common pyrrole derivative," Jour. Chem. Soc., pp. 483-487, 1978	

	T	1	
Examiner Signature	/James Anderson/	Date Considered	04/19/2007

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

<sup>&</sup>lt;sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Sub	titute for form 1449A/PT(	0	Complete if Known		
	- ODMATION		Application Number	10/042,226	
	= '''	DISCLOSURE	Filing Date	January 11, 2002	
SI	STATEMENT BY APPLICANT		First Named Inventor	Bernd RIEDL et al.	
		,	Group Art Unit	1614	
	(use as many she	eets as necessary)	Examiner Name	Dwayne C. Jones	
She	et 3	of 8	Attorney Docket Number	BAYER-0024-A	

		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner Cite the item (book, magazine, journal, serial, syr number(s), publisher, city		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
-		XP 002233466, MEDLINEARM, NLM0336009 [Initia-arterial ACNU, CDDP chemotherapy	
		for brains metastases from lung cancer: comparison of cases with and without intra arterial	
/JDA/		XP-002086152 Hanson, "Pulmonary-Allergy, Dermatological, Gastrointestinal & Arthritis, Inhibitors of p38 kinase," <i>Exp. Opin. Ther. Patents</i> , (1997) 7(7):729-733	
/JDA/		T. Murata et al., "Facile synthesis of new pyrrolo[3,4-d]pyrimidine-2,4-diones", Chemical and Pharmaceutical Bulletin, Vol. 22, 1974, pp. 1212-13 (XP-000973679)	
		Wilson, Keith et al., "The structural basis for the specificity of pyrimidinylimidazole	
	1	Inhibitors of p38 MAP Kinase" AP-002103155	<del>                                     </del>
50A		Lowinger, T. B.; Riedl, B.; Wood, J.; Dumas, J.; Smith, R. A.; Khire, U.; Bankston, D.; Monahan, M.K.; Scott, W. J.; Lee, W.; Johnson, J. S.; Caringal, Y.; Turner, T.; Gane, T.; Kennure, N.; Barbosa, J. "Discovery of a Novel Class of Potent Raf Kinase inhibitors: Structure Activity Relationships" Clin. Cancer Res. 2000, 6(suppl.) 335.	
/JDA/		Redman, A. M.; Johnson, J. S.; Dally, R.; Swartz, S.; Wild, H.; Paulsen, H.; Caringal, Y.; Gunn, D.; Renick, J.; Osterhout, M.; Kingery-Wood, J.; Smith, R. A.; Lee, W.; Dumas, J.; Wilhelm, S. M.; Housley, T. J.; Bhargava, A.; Ranges, G. E.; Shrikhande, A.; Young, D.; Bombara, M.; Scott W. J. "P38 Kinase Inhibitors for the Treatment of Arthritis and Osteoporosis: Thienyl, Furyl and Pyrrolyl Ureas" Bioorg. Med. Chem. Lett. 2001, 11 (1), 9.	
/JDA/		Dumas, J.; Hatoum-Mokdad, H.; Sibley, R. N.; Smith, R. A.; Scott, W. J.; Khire, U.; Lee, W.; Wood, J.; Wolanin, D.; Cooley, J.; Bankston, D.; Redman, A. M.; Schoenleber, R.; Caringal, Y.; Gunn, D.; Romero, R.; Osterhout, M.; Paulsen, H.; Housley, T. J.; Wilhelm, S. M.; Bhargava, A.; Pirro, J.; Chien, DS.; Ranges, G. E.; Shrikhande, A.; Muzsi, A.; Bortolon, E.; Wakefield, J.; Gianpaolo-Ostravage, C.; Chau, T. "Synthesis and Pharmacological Characterization of a Potent, Orally Active p38 Kinase Inhibitor" Bioorg. Med. Chem. Lett. 2002, 12, 1559.	

Examiner Signature	/James Anderson/	Date Considered	04/19/2007

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

RJT/lvb:Document4

<sup>&</sup>lt;sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Approved for use through 10/31/2002. OMB 0551-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO		Complete if Known
	Application Number	10/042,226
INFORMATION DISCLOSURE	Filing Date	January 11, 2002
STATEMENT BY APPLICANT	First Named Inventor	Bernd RIEDL et al.
	Group Art Unit	1614
(use as many sheets as necessary)	Examiner Name	Dwayne C. Jones
Sheet 4 of 8	Attorney Docket Number	BAYER-0024-A

		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner Cite No.1			
/JDA/		Lowinger, T. B.; Riedl, B.; Dumas, J.; Smith, R. A. "Design and Discovery of Small Molecules Targeting Raf-1 Kinase" Curr. Pharm. Design 2002, 8 (25), 2269.	
Bankston, D.; Dumas, J.; Natero, R.; Riedl, B.; Monahan, MK.; Sibley, R. "A Scaleable Synthesis of BAY 43-9006: A Potent Raf Kinase Inhibitor for the Treatment of Cancer" Org. Proc. Res. Dev. 2002, 6(6), 777-781.			
		Khire, U.; Bankston, D.; Barbosa, J.; Brittelli, D.; Caringal, Y.; Carlson, R.; Dumas, J.; Gane, T.; Heald, S.; Hibner, B.; Johnson, J. S.; Katz, M. E.; Kennure, N.; Kingery-Wood, J.; Lee, W.; Liu, XG.; Lowinger, T. B.; Renick, J.; McAlexander, I.; Monahan, MK.; Natero, R.; Riedl, B.; Rong, H.; Sibley, R. N.; Smith, R. A.; Wolanin, D.: "Omega-Carboxypyridyl Substituted Ureas as Raf Kinase Inhibitors: SAR of the Amide Substituent" Bioorg. Med. Chem. Lett. 2004, 14, 783-786.	
,		Dumas, J.; Smith, R. A.; Lowinger, T. B.: "Recent Developments in the Discovery of Protein Kinase Inhibitors from the Urea Class" Curr. Opin. Drug Discov. Dev. 2004, 7(5), 600-616.	
		Wan PTC, Garnett MJ, Roe SM, Lee S, Niculescu-Duvaz D, Good VM, Cancer genome project, Jones CM, Marshall CJ, Springer CJ, Barford D, Marais R: Mechanism of activation of the RAF-ERK signaling pathway by oncogenic mutations of B-RAF. Cell 2004, 116, 855-867.	
		Mross K, Steinbild S, Baas F, Reil M, Buss P, Mersmann S, Voliotis D, Schwartz B, Brendel E: "Drug-drug interaction pharmacokinetic study with the Raf kinase inhibitor (RKI) BAY 43-9006 administered in combination with irinotecan (CPT-11) in patients with solid tumors" Int. J. Clin. Pharm. Ther. 2003, 41(12), 618-619.	
/JDA/		Siu LL, Awada A, Takimoto CH, Moore MJ, Piccart M, Fiander W, Lathia C, Petrensiuc O: "Phase I study of oral Raf-1 kinase inhibitor BAY 43-9006 in combination with gemcitabine in patients with advanced solid tumors" 39th ASCO meeting, Chicago, IL (2003) Abstract 828.	

Examiner Signature	/James Anderson/	Date Considered	04/19/2007

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

RJT/lvb:Document4



<sup>1</sup> Unique citation designation number. 2 Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449A/PTO		Complete if Known		
	Application Number	10/042,226		
INFORMATION DISCLOSUR	Filling Date	January 11, 2002		
STATEMENT BY APPLICAN	First Named Inventor	Bernd RIEDL et al.		
	Group Art Unit	1614		
(use as many sheets as necessary)	Examiner Name	Dwayne C. Jones		
Sheet 5 of 8	Attorney Docket Number	BAYER-0024-A		

		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS		
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²	
/JDA/		Richly H, Kupsch P, Passage K, Grugert M, Hilger RA, Kredke S, Voliotis D, Scheulen ME, Seeber S, Strumberg D: "A Phase I clinical and pharmacokinetic study of the Raf kinase inhibitor (RKI) BAY 43-9006 administered in combination with doxorubicin in patients with solid tumors" Int. J. Clin. Pharm. Ther. 2003, 41(12), 620-621.		
		Sorbera LA, Castaner J, Bozzo J, Leeson PA: "Oncolytic Raf kinase inhibitor" Drugs Future 2002, 27, 1141-1147.		
		Bollag G, Freeman S, Lyons JF, Post LE: "Raf pathway inhibitors in oncology" Curr. Opin. Invest. Drugs 2003, 4(12), 1436-1441.		
		Lee JT, McCubrey JA: BAY-43-9006 (Bayer/Onyx). Curr Opin Invest Drugs (2003) 4(6):757-763.		
		DeGrendele H: "Activity of the Raf kinase inhibitor BAY 43-9006 in patients with advanced solid tumors" Clin. Colorectal Cancer 2003, 3(1), 16-18.		
		Wilhelm, S. M.; Carter, C.; Tang, L.Y.; Wilkie, D.; McNabola, A.; Rong, H.; Chen, C.; Zhang, X.; Vincent, P.; McHugh, M.; Cao, Y.; Shujath, J.; Gawlak, S.; Eveleigh, D.; Rowley, B.; Liu, L.; Adnane, L.; Lynch, M.; Auclair, D.; Taylor, I.; Gedrich, R.; Voznesensky, A.; Riedl, B.; Post, L. E.; Bollag, G.; Trail, P.A. "BAY 43-9006 exhibits broad spectrum oral antitumor activity and targets the RAF/MEK/ERK pathway and receptor tyrosine kinases involved in tumor progression and angiogenesis" Cancer Res. 2004, 64(19), 7099-7109.		
		Dumas, J.; Sibley, R.; Riedl, B.; Monahan, MK.; Lee, W.; Lowinger, T. B.; Redman, A. M.; Johnson, J. S.; Kingery-Wood, J.; Scott, W. J.; Smith, R. A.; Bobko, M.; Schoenleber, R.; Ranges, G. E.; Housley, T. J.; Bhargava, A.; Wilhelm, S. M.; Shrikhande, A. "Discovery of a New Class of p38 Kinase Inhibitors" Bioorg. Med. Chem. Lett. 2000, 10 (18), 2047.		
/JDA/		Proceedings of the American Association for Cancer Research - Volume 42 - March 2001 - #4957 A Novel Diphenylurea Raf-1 Kinase Inhibitor (RKI) Blocks the Raf/Mek/Erk Pathway in Tumor Cells. Scott McClelland Wilhelm et al., Bayer Corporation.		

			· · · · · · · · · · · · · · · · · · ·
Examiner Signature	/James Anderson/	Date Considered	04/19/2007

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231, DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



<sup>1</sup> Unique citation designation number, 2 Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449A/PTO	Complete if Known		
INFORMATION BIOOLOGUEE	Application Number	10/042,226	
INFORMATION DISCLOSURE	Filing Date	January 11, 2002	
STATEMENT BY APPLICANT	First Named Inventor	Bernd RIEDL et al.	
	Group Art Unit	1614	
(use as many sheets as necessary)	Examiner Name	Dwayne C. Jones	
Sheet 6 of 8	Attorney Docket Number	BAYER-0024-A	

		NONPATENT LITERATURE DOCUMENTS	er inter
Examiner Initials *	Cite No.¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Т2
/JDA/ Nickel et al., "Carboxylic acid analogues of suramin, potential filaricides," <i>Indian Journal Chemistry</i> , Vol. 30B, February 1991, p. 182-187		Nickel et al., "Carboxylic acid analogues of suramin, potential filaricides," Indian Journal of	•
/JDA/		Campbell et al., "Increasing complexity of Ras signaling," Oncogene, (1998) 17, 1395-1413	
		Moeiling et al., "Signal transaction as target of gene therapy," Institute of Medical Virology, University of Zürich, Recent Results in Ouncer Research, Vol. 142, pp. 08-74	
		Jay H. Stein, Internal Medicine, 4th Edition, 1994, pp. 699-715	
/JDA/		Kempter et al., "Synthese potentieller Pflanzenschutz- und Schädlingsbekämpfungsmittel aus substituierten Anilinen," Pädagosische Hochschule, Eingegangen am 1.7.1982, 101-120	
		Lyons et al., "Discovery of a novel Raf kinase inhibitor," Endocrine-Related Cancer, (2001) 8, 219-225	
		Smith, et al., "Discovery of heterocyclic ureas as a new class of raf kinase inhibitors: identification of a second generation lead by a combinatorial chemistry approach."  Bioorganic & Medicinal Chemistry Letters, 11 (2001) 2775-2778	
		Adjei et al., "A phase I study of BAY 43-9006 and gefitinib in patients with refractory or recurrent non-small-cell lung cancer (NSCLC)," Meeting: 2005 ASCO Annual Meeting, Category: Developmental Therapeutics: Molecular Therapeutics, Subcategory: Antiangiogenic or Antimetastatic agents, Abstract No. 4510	
		Eisenhauer et al., "Impact of new non-cytotoxics in the treatment in ovarian cancer," Int. J. Gynecol Cancer, 2001, 11 (Suppl. 1), 68-72	
		Strumberg et al., "Results of phase I pharmacokinetic and pharmacodynamic studies of the raf kinase inhibitor BAY 43-9006 in patients with solid tumors," International Journal of Clinical Pharmacology and Therapeutics, Vol. 40, No. 12/2002 (580-581)	
$\sqrt{}$		Chang et al., "BAY 43-9006 (Sorafenib) inhibitors ectopic (s.c.) and orthotopic growth of a murine model of renal adenocarcinoma (Renca) predominantly through inhibition of tumor angiogenesis," 96th Annual Meeting, April 16-20, 2005, Anaheim/Orange County, CA	
/JDA/		Panka et al., "BAY 43-9006 induces apoptosis in melanoma cell lines," 96th Annual Meeting, April 16-20, 2005, Anaheim/Orange County, CA	

Examiner Signature	/James Anderson/	Date Considered	04/19/2007
-----------------------	------------------	--------------------	------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



<sup>1</sup> Unique citation designation number. 2 Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449A/PTO	Complete if Known		
WEODMATION DIGGLOCUES	Application Number	10/042,226	
INFORMATION DISCLOSURE	Filing Date	January 11, 2002	
STATEMENT BY APPLICANT	First Named Inventor	Bernd RIEDL et al.	
	Group Art Unit	1614	
(use as many sheets as necessary)	Examiner Name	Dwayne C. Jones	
Sheet 7 of 8	Attorney Docket Number	BAYER-0024-A	

		NON PATENT LITERATURE DOCUMENTS
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
/JDA/		Auclair, et al., "BAY 43-9006 (Sorafenib) is a potent inhibitor of FLT3 tyrosine kinase signaling and proliferation in AML cells," 96 <sup>th</sup> Annual Meeting, April 16-20, 2005, Anaheim/Orange County, CA
/JDA/		Murphy et al., "BAY 43-9006 controls tumor growth through inhibition of vascular development," 96 <sup>th</sup> Annual Meeting, April 16-20, 2005, Anaheim/Orange County, CA
/JDA/		Spronsen et al., "Novel treatment strategies in clear-cell metastatic renal cell carcinoma,"  Anti-Cancer Drugs, 2005, 16:709-717
/JDA/		Thaimattam et al., "3D-QSAR CoMFA, CoMSIA studies on substituted ureas as Raf-1 kinase inhibitors and its confirmation with structure-based studies," <i>Bioorganic &amp; Medicinal Chemistry</i> , 12(2004) 6415-6425
/JDA/		Danson et al., "Improving outcomes in advanced malignant melanoma," <i>Drugs</i> , 2005, 65(6):733-743
/JDA/		Heim et al., "Antitumor effect and potentiation or reduction in cytotoxic drug activity in human colon carcinoma cells by the Raf kinase inhibitor (RKI) BAY 43-9006," International Journal of Clinical Pharmacology and Therapeutics, Vol. 41, No. 12/2003 (616-617)
		Richly et al., "Results of a phase I trial of DAY 43-9000 in combination with dexorablein in patients with primary hapatic cancer," International Journal of Clinical Pharmacology and Thorapoutics, Vol. 42, No. 11/204 (650-651)
		Hubbard, "Oncogonic mutations in B-Raf. some losses yield gains," Skirball Institute of Biomelecular Medicine and Department of Pharmacology, New York University Ochool of Medicine, New York, NY
/JDA/		Thompson et al., "Recent progress in targeting the Raf/MEK/ERK pathway with inhibitors in cancer drug discovery," Curr. Opin. Pharmacol., 2005 Aug., 5(4):350-6
/JDA/		Moore et al., "Phase I study to determine the safety and pharmacokinetics of the novel Raf kinase and VEGFR inhibitor BAY 43-9006, administered for 28 days on/7 days off in patients with advanced, refractory solid tumors," <i>Annals of Oncology</i> , 16:1688-1694, 2005
/JDA/		Ahmad et al., "Kinase inhibition with BAY 43-9006 in renal cell carcinoma," Clinical Cancer Research, Vol. 10, 6388s-6392s, 15 Sept. 2004

Examiner /James Anderson/	Date Considered	04/19/2007
---------------------------	--------------------	------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



<sup>1</sup> Unique citation designation number. 2 Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449A/PTO				Complete if Known		
INFORMATION DISCLOSURE				Application Number	10/042,226	
	•••			Filing Date	January 11, 2002	
STATEMENT BY APPLICANT			PPLICANT	First Named Inventor	Bernd RIEDL et al.	
				Group Art Unit	1614	
	use as many she	ets as	necessary)	Examiner Name	Dwayne C. Jones	
Sheet	8	of	8	Attorney Docket Number	BAYER-0024-A	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the erticle (when appropriate), title of the item (book, magazine, journel, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T 2
/JDA/		Clark et al., "Safety and pharmacokinetics of the dual action raf kinase and vascular endothelial growth factor receptor inhibitor, BAY 43-9006, in patients with advanced, refractory solid tumors," Clin. Cancer Res., 2005:11(15), 1 August 2005, 5472-5480	
/JDA/		Wilhelm et al., "BAY 43-9006: preclinical data," Curr Pharm Des, 2002, 8(25):2255-7	
/JDA/		Wright et al., "Clinical trials referral resource. Current clinical trials of BAY 43-9006, Part 1," Oncology, 2005 Apr, 19(4):499-502	
/JDA/		Patent Abstracts of Japan, Publication No. 02-023337, published 01-28-1990	
/JDA/		Patent Abstracts of Japan, Publication No. 02-022650, published 01-25-1990	
/JDA/		Wissner et al., "Analogues of platelet activating factor. 7. Bis-aryl amide and bis-aryl urea receptor antagonists of PAF," <i>J. Med. Chem.</i> , 1992, 35, 4779-4789	
		Ravi et al., Activated raf- i causes growtin arrest in human small cell lung cancer cells, J.  Slin. Invest., pp. 153-159	
		Lemoine, "Overview of ras oncogenes and their clinical potential," Chapter 10,	
/JDA/		Escudier et al., "Randomized phase III trial of the raf kinase and VEGFR inhibitor sorafenib (BAY 43-9006) in patients with advanced renal cell carcinoma (RCC)," Meeting: 2005 ASCO Annual Meeting, Category: Genitourinary Cancer, Subcategory: Kidney Cancer, Abstract No. 4510	
/JDA/		Eisen et al., "Phase I trial of BAY 43-9006 (sorafenib) combined with dacarbazine (DTIC) in metastatic melanoma patients," Meeting: 2005 ASCO Annual Meeting, Category: Melamona, Subcategory: Melamona, Abstract No. 7508	

Examiner Signature	/James Anderson/	Date Considered	04/19/2007

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



<sup>&</sup>lt;sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.